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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,410	05/18/2006	Ake Oberg	49741.13.1	5477
22859 7590 11/15/2007 INTELLECTUAL PROPERTY GROUP FREDRIKSON & BYRON, P.A. 200 SOUTH SIXTH STREET SUITE 4000 MINNEAPOLIS, MN 55402			EXAMINER LLOYD, EMILY M	
			ART UNIT 3736	PAPER NUMBER
			MAIL DATE 11/15/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/560,410	Applicant(s) OBERG ET AL.	
	Examiner Emily M. Lloyd	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>08/22/2006 10/23/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: I_C , I_P , and I_D . Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.
2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: θ , R_1 , p , c , and R_2 . Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet"

or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

3. The drawings are objected to because Figures 8A, 8B, and 8C appear to have lines pointing to components that are missing labels. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

4. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

5. The abstract of the disclosure is objected to because it should contain complete sentences (the first line "Device for..." should be "A device for..." and the 7th line "Method for..." should be "A method for..."); should not contain the words "said" and "means"; and has too many words. Correction is required. See MPEP § 608.01(b).

6. The disclosure is objected to because of the following informalities: page 1 line 12 "threshold" should be "thresholds"; page 2 line 12 "Sorrel et al Bacteria" should be "Sorrel et al., Bacteria"; page 2 line 15 the word "model" should be followed by a comma instead of a period; page 3 lines 15-16 should be revised for clarity; page 5 line 19 is missing the "(" to correspond to the ")"; page 5 line 28 it appears that a word (a specific number, or the word "many") should be inserted before the word "different"; page 6 lines 11 and 15 "λ:s" should be "λs"; page 6 line 14 the ".,." after "TM" should be deleted; page 6 line 16 it appears that the "four-wavelength system" should instead refer to a "five-wavelength system"; page 7 line 16 the word "emitting" should be inserted after "light"; page 8 line 3 "of" should be "on"; page 8 lines 24-26 should be revised for clarity; page 10 line 29 it appears that "on at a time" should be "on one at a time"; page 11 lines 3-4 should be revised for clarity; page 11 line 11 "shape" should be "shapes"; page 11 line

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13 it appears that "electing" should be "selecting"; page 11 lines 27-29 the language "every second" should be replaced for one part of the sentence (suggestion: change the second "every second" to "each remaining"); page 12 line 9 "to" should be inserted after "possible"; page 12 line 31 the word "where" should be inserted after "auditory canal 14"; and page 13 line 1 "a" should be inserted after "perform".

Appropriate correction is required.

Claim Objections

7. Claims 1-16 are objected to because of the following informalities: claims 1 and 15 should begin with the word "A" and claims 2-14 and 16 should begin with the word "The"; claim 1 line 9 "that" should be "where"; claim 5 line 2 "at" should be deleted or changed to "at least"; claim 6 line 6 it appears that a limitation regarding the first set of illumination fibres and the second set of detecting fibres is missing; claim 6 lines 8-9 "said signal processor" lacks antecedent basis; claim 7 lines 1 and 3 "said" should be inserted before "first"; claim 8 line 2 "tar- get" should be "target"; claim 9 line 5 it appears that "electing" should be "selecting"; claim 11 line 2 the comma after "fibres" should be deleted; and claim 13 line 2 the comma after "fibres" should be deleted.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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9. Claims 7 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 line 4 it is unclear what "inter-leaved" means.

Claim 16 line 1 claims the method in accordance with claim 14. As claim 14 is a device claim and claim 15 is a method claim, the Examiner is interpreting claim 16 as depending on claim 15 instead of claim 14.

Claim 16 lines 8-9 it is unclear what "type bodies having different shapes" means. For the purpose of examination, the Examiner has interpreted this to mean "different shapes".

Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claim 1 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/587490. Although the conflicting claims are not identical, they are not patentably distinct from each other because both devices have a probe, a plurality of optical fibers, and a detector means for measuring the intensity of light reflected from the body.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by United States Patent 5673692 (Schulze et al.).

Regarding claim 1, Schulze et al. discloses a device for measuring physical properties of the tympanic membrane (TM), comprising an elongated probe (Figures 6 and 10) with a distal end for inspection of the ear, wherein a plurality of optical fibers is arranged in said elongated probe characterized in that the plurality of fibers includes either a first set of fibers for conveying light from a light source to said distal end of said probe and a second set of fibers for conveying light reflected from the tympanic membrane in front of said distal end to a first detector means, or a set of fibers both for conveying light from a light source to said distal end of said probe and for conveying

light reflected from the tympanic membrane in front of said distal end to a first detector means (photosensor 32 Figure 2), that said first detector means is designed for measuring the intensity of light reflected from the tympanic membrane (Column 4 lines 16-24).

14. Claims 15 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by United States Patent 6319199 (Sheehan et al.).

Regarding claim 15, Sheehan et al. disclose a method for measuring physical properties of the tympanic membrane (TM) (Column 1 lines 8-12), including the following steps: a) illuminating the tympanic membrane with light from a light source (Column 5 lines 46-48), b) detecting light reflected from the tympanic membrane (Column 5 lines 47-67), and c) analyzing the intensity at selected wavelengths or a spectrum of wavelengths (Column 6 lines 46-59).

Regarding claim 16, Sheehan et al. disclose the method in accordance with claim 15, also including the following steps: a) illuminating in sequence individual spots distributed over the tympanic membrane (Column 5 lines 25-36), b) detecting the intensity of light reflected from the spots of the tympanic membrane (Column 5 lines 26-67) and c) determining the shape of the tympanic membrane by comparing said detected intensities with stored intensities obtained from type bodies having different shapes (Column 6 lines 47-59).

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

16. Claim 15 is rejected under 35 U.S.C. 102(e) as being anticipated by United States Patent 7058441 (Shahar et al.).

Regarding claim 15, Shahar et al. disclose a method for measuring physical properties of the tympanic membrane (TM) (Column 2 lines 9-13), including the following steps: a) illuminating the tympanic membrane with light from a light source (Column 3 line 65 – Column 4 line 2), b) detecting light reflected from the tympanic membrane (Column 4 lines 34-51), and c) analysing the intensity at selected wavelengths or a spectrum of wavelengths (Column 4 line 49 – Column 5 line 8).

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

18. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

19. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

20. Claims 1, 4-8, 10, and 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shahar et al. in view of Schulze et al.

Regarding claim 1, Shahar et al. disclose a device for measuring physical properties of the tympanic membrane (TM), comprising an elongated probe (device 20 Figure 2) with a distal end (distal end 23 Figure 2) for inspection of the ear (substantially frustoconically shaped inner tip housing 24 Figure 2), wherein a plurality of optical fibers is arranged in said elongated probe characterized in that the plurality of fibers includes a second set of fibers (optical fiber 11 Figure 2) for conveying light reflected from the tympanic membrane in front of said distal end to a first detector means (spectrometer 30 via electro-optical cable 25', Figures 2 and 3), where said first detector means is designed for measuring the intensity of light reflected from the tympanic membrane (Column 4 lines 34-51).

Shahar et al. does not explicitly disclose that a first set of fibers for conveying light from a light source to said distal end of said probe is used. Schulze et al. teach the

use of a first set of fibers for conveying light from a light source to said distal end of said probe (Column 4 lines 19-22). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use such a first set of fibers for conveying light from a light source to said distal end of said probe as taught by Schulze et al. in the invention of Shahar et al. to provide the predictable result of illuminating the tympanic membrane (Shahar et al. Column 4 lines 1-2).

Regarding claim 4, Shahar et al. as modified by Schulze et al. teach a device in accordance with claim 1, wherein said first detector means comprises at least two separate detectors, a first detector having a peak sensitivity at 650 nm and a second detector having a peak sensitivity at 576 nm (Shahar et al. Column 4 lines 45-47, 1024 or 2048 photoelements over the spectrum of 400 nm to 1200 nm (Column 3 line 18) would result in at least one detector at each of these peak sensitivities).

Regarding claim 5, Shahar et al. as modified by Schulze et al. teach a device in accordance with claim 4, wherein said first detector means comprises at least five separate detectors, a first detector having a peak sensitivity around 650 nm, a second detector having a peak sensitivity around 460 nm, a third detector having a peak sensitivity around 490 nm, a fourth detector having a peak sensitivity around 542 nm, and a fifth detector having a peak sensitivity around 576 nm (Shahar et al. Column 4 lines 45-47, 1024 or 2048 photoelements over the spectrum of 400 nm to 1200 nm (Column 3 line 18) would result in at least one detector at each of these peak sensitivities).

Regarding claim 6, Shahar et al. as modified by Schulze et al. teach a device in accordance with claim 1, wherein the plurality of fibers includes a first set of illumination fibers (Schulze et al. "optical fibers" Column 4 lines 19-22), each of said illumination fibers being connected in a first end to one of a plurality of individually controllable light sources (Schulze et al. first and second radiation sources 34 and 36 Figure 2), and a second set of detecting fibers (Shahar et al. at least one optical fiber 11 and electro-optical cable 25' Figures 2 and 3), said second set of detecting fibers being connected in a first end to individual detectors (Shahar et al. Column 4 lines 45-47; Schulze et al. photosensor 32 Figure 2), wherein said individually controllable light sources (Schulze et al. first and second radiation sources 34 and 36 Figure 2) are connected to a control unit (Schulze et al. POS preprocessor 38/58 Figure 2) arranged to switch on said individually controllable light sources in a sequence (Schulze et al. Column 4 lines 30-33) and wherein said individual detectors (Schulze et al. photosensor 38 Figure 2) are connected to said signal processor for conveying signals responsive to the intensity of incident light reflected from the tympanic membrane (Schulze et al. Column 4 lines 38-49).

Regarding claims 7, 10, and 12, Shahar et al. as modified by Schulze et al. teach a device in accordance with claim 6. Shahar et al. as modified by Schulze et al. are mute as to the arrangement of optical fibers within the distal end of the probe.

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to arrange the optical fibers of Shahar et al. as modified by Schulze et al. in various configurations because Applicant

has not disclosed that any particular configuration provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Shahar et al. as modified by Schulze et al.'s probe, and applicant's invention, to perform equally well because all optical fiber configurations would perform the same function of providing light to and relaying light reflected from the tympanic membrane equally well.

Therefore, it would have been prima facie obvious to modify Shahar et al. as modified by Schulze et al. to obtain the invention as specified in claims 7, 10, and 12 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Shahar et al. as modified by Schulze et al.

Regarding claim 8, Shahar et al. as modified by Schulze et al. teach a device in accordance with claim 6, wherein said first set of illumination fibers is arranged to direct emitted light in the form of a line on to a target surface (Schulze et al. Column 4 lines 19-22; light will travel linearly after leaving the optical fiber).

Regarding claim 13, Shahar et al. as modified by Schulze et al. teach a device in accordance with claim 8, wherein a separate optical fiber, or set of fibers, is operatively connected to a second light source for conveying light that is directed towards target tissue as a visual reference (Shahar et al. halogen lamp Column 3 line 67).

Regarding claim 14, Shahar et al. as modified by Schulze et al. teach a device in accordance with claim 1, wherein said probe extends from a vertical grip section (Shahar et al. elongated housing 22 Figure 2) and an eyepiece (Shahar et al. eyepiece

of otoscope 20 Figure 2) is optically connected to an ocular channel extending through said probe (Shahar et al. Figure 2, also Figures 4 and 5).

21. Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schulze et al. in view of Shahar et al.

Regarding claim 2, Schulze et al. discloses the device in accordance with claim 1, wherein said first detector means is a single detector for detecting the light intensity at selected wavelengths or at a spectrum of wavelengths (photosensor 32 Figure 2), that is connected to a signal processor (processor 24 Figure 2) provided in a control apparatus (monitor system 20 with pulse oximetry sensor (POS) preprocessor 38/58 Figure 2).

Schulze et al. do not disclose that said signal processor is configured to apply an erythema detection algorithm on data acquired from said first detector means. Shahar et al. teach a signal processor that is configured to apply an erythema detection algorithm on data acquired from said first detector means (Column 7 line 39 – Column 8 line 18). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use such a signal processor configured to apply an erythema detection algorithm on data acquired from said first detector means as taught by Shahar et al. in the invention of Schulze et al. to provide the predictable result of alerting medical personnel if the patient has an ear infection (Shahar et al. Column 7 lines 39-49).

Regarding claim 3, Schulze et al. as modified by Shahar et al. teach a device in accordance with claim 2, wherein said erythema detection algorithm utilizes the fact that

the photon absorption in the vicinity of the Soret band and the Q band of various blood chromophores is different in erythematous and in normal tissue (Shahar et al. Column 3 line 18, Column 4 lines 45-47, and Column 7 lines 5-25).

22. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shahar et al. as applied to claim 15 above, and further in view of United States Patent 6319199 (Sheehan et al.).

Regarding claim 16, Shahar et al. disclose the method in accordance with claim 15. Sheehan et al. teach the following steps: a) illuminating in sequence individual spots distributed over the tympanic membrane (Column 5 lines 25-36), b) detecting the intensity of light reflected from the spots of the tympanic membrane (Column 5 lines 26-67) and c) determining the shape of the tympanic membrane by comparing said detected intensities with stored intensities obtained from type bodies having different shapes (Column 6 lines 47-59). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the steps of Sheehan et al. in the invention of Shahar et al. to provide the predictable result of providing additional information to assist with the diagnosis of ear infections (Sheehan et al. Column 1 lines 29-38).

23. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shahar et al. as modified by Schulze et al. as applied to claims 1, 4-8, 10, and 12-14 above, and further in view of Sheehan et al.

Regarding claim 9, Shahar et al. as modified by Schulze et al. teach a device in accordance with claim 6. Sheehan et al. teach the use of a memory unit (memory 210

Figure 2, also Column 7 lines 19-21) provided for storing signals responsive to the intensity of incident light reflected from a plurality of bodies having different and specified concave and convex surfaces together with the corresponding surface data, and wherein said control unit (processor 208 Figure 2) is designed for comparing said stored signals with signals obtained from a tympanic membrane and electing the surface having a correspondence with the signals obtained from a tympanic membrane (Column 6 lines 47-59). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use such a memory unit and control unit for determining if the tympanic membrane is concave or convex as taught by Sheehan et al. in the invention of Shahar et al. as modified by Schulze et al. to provide the predictable result of providing additional information to assist with the diagnosis of ear infections (Sheehan et al. Column 1 lines 29-38).

24. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shahar et al. as modified by Schulze et al. and Sheehan et al. as applied to claims 1, 4-10, and 12-14 above, and further in view of United States Patent 5044373 (Northeved et al.).

Regarding claim 11, Shahar et al. as modified by Schulze et al. and Sheehan et al. teach a device in accordance with claim 9. Shahar et al. as modified by Schulze et al. and Sheehan et al. do not disclose a separate optical fiber, or set of fibers, is arranged on either side of said ocular channel diametrically opposed to each other for directing light towards the tympanic membrane and for producing visual reference points on the tympanic membrane. Northeved et al. teach a separate light conductor arranged on either side of a channel diametrically opposed to each other for directing

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light towards the tympanic membrane (light conductors 21 around clearance 33 of tube 25, Figure 7), that are capable of producing visual reference points on the tympanic membrane. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use such a separate light conductor arranged on either side of a channel diametrically opposed to each other as taught by Northeved et al. in the invention of Shahar et al. as modified by Schulze et al. and Sheehan et al. to provide the predictable result of easier identification of structures within the ear and distances between the probe and the ear.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily M. Lloyd whose telephone number is 571-272-2951. The examiner can normally be reached on Monday through Friday 8:30 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Emily M Lloyd
Examiner
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/EML/

A handwritten signature in black ink, appearing to read 'Emily M Lloyd', is located in the lower right quadrant of the page.